

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

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| Applicant's or agent's file reference NHC0083-PCT | | Date of mailing (day/month/year) 20 APR 2007 |
| FOR FURTHER ACTION See paragraph 2 below | | |
| International application No. PCT/US04/32160 | International filing date (day/month/year) 02 October 2004 (02.10.2004) | Priority date (day/month/year) 02 October 2003 (02.10.2003) |
| International Patent Classification (IPC) or both national classification and IPC IPC: A61M 11/00(2006.01) USPC: 128/200.23 | | |
| Applicant IVAX CORPORATION | | |

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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| Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201 | Date of completion of this opinion 04 April 2007 (04.04.2007) | Authorized officer Justine Yu <i>Sharon M. Greene</i> Telephone No. 571-727-3700 |
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Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/32160

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
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Box No. II Priority

1. ☐ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☒ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:
The priority claim has been found invalid because the filing date of the priority application is outside the time period provided in PCT Rule 4.10.

WRITTEN OPINION OF THE
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International application No.
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Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 4-13,15,16,18,21,23-29,32-38 YES

Claims 1-3,14,17,19,20,22,30,31 NO

Inventive step (IS)

Claims 4-13,15,16,18,21,23-29,32-38 YES

Claims 1-3,14,17,19,20,22,30,31 NO

Industrial applicability (IA)

Claims 1-38 YES

Claims NONE NO

2. Citations and explanations:

Please See Continuation Sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

"the abutment" of claim 3 lacks antecedent basis;
claims 10,26,27,36, are 38 multiple dependent.

WRITTEN OPINION OF THE
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International application No.
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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Claims 1-3,14,17,19,20,22,30, and 31 lack novelty under PCT Article 33(2) as being anticipated by Hyppola US 6,332,461 B1.

As to claim 1, Hyppola discloses a dry powder inhalation apparatus in figure 1, comprising a reservoir (1) for medicament, a mouthpiece (col.2 line 67) for insertion in the mouth of a user for inhalation of a predetermined dose of medicament, a delivery channel (2) between a discharge outlet (outlet of the reservoir 1) of the reservoir and the mouthpiece for delivering said predetermined dose of medicament, a device (6) normally held adjacent the reservoir for receiving said predetermined dose of medicament from said discharge outlet and transferring it to the delivery channel, and a mechanism (9,10) adapted to release the device and permit controller movement thereof to the delivery channel for said delivery.

As to claim 2, Hyppola discloses the apparatus further comprising a cup (3) for receiving the said dose and a longitudinally slideable body (4) counting said cup.

As to claim 3, Hyppola discloses the apparatus further comprising the abutment means being bodily movable by an actuation means (7)

As to claim 14, Hyppola discloses wherein the actuation means comprises a resiliently mountable slidable member (11) which as a tab (tabs engaging 11, see fig.1) projecting through a bore of a body (7) of the apparatus for releasing the device.

As to claim 17, Hyppola discloses wherein the actuation means comprises a resiliently and pivotable mounted detent means (9,10) which is shiftable bodily about its pivot axis to release the device.

As to claim 19, Hyppola discloses wherein the actuating means comprises a resiliently mounted plunger means (7,8,11) which has one end projecting through a bore in a body of the device and an opposite end adapted to engage the device for shifting same bodily to said delivery channel (see fig.1).

As to claim 20, Hyppola discloses wherein the plunger means has a substantially cylindrical body member connecting the one end and the opposite end, the opposite end being enlarged relative to the body member (see fig.1).

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Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

As to claim 22, Hyppola discloses wherein the actuation means comprises an elector-mechanical means (8-11),

As to claim 30, Hyppola discloses the apparatus further comprising a breath actuable apparatus (col.3 lines 8-12).

As to claim 31, Hyppola discloses wherein the mechanism is between opposed spaced walls of the reservoir and has a member which is retractable on a user talking a breath on the mouthpiece (col. 2, lines 65-67; col.3 lines 1-17).

Claims 4-13,15,16,18,21,23-29, and 32-38 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the subject matter cited in the stated claims.

Claims 1-38 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.